

REMARKS

I. Status of the Claims

Claims 39-58 are pending.¹ No claim has been amended in this Response.

Applicant respectfully requests reconsideration of the application and timely allowance of the claims in light of the following remarks.

II. Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 39-58 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 6,475,234 to Richter et al. ("Richter") in view of U.S. Patent No. 5,919,126 to Armini ("Armini") for the reasons disclosed on pages 2-4 of the Office Action.

The Examiner alleges that Richter "disclose a stent being made from superelastic alloy" and "suggest the stent being in the form of a patterned tube having a plurality of radially expandable cylindrical elements and interconnected by elements disposed between [sic] and the stent" and "the stent plated with radiopaque materials." See Office Action at page 2. (citation omitted) Armini, on the other hand, discloses a metallic adhesive layer between the radiopaque layer and the stent substrate. *Id.* at page 2.

The Examiner thus asserts that "the product of Richter in view of Armini is a stent having three layers, a superelastic alloy substrate tube, a first metallic layer, and a

¹ The Office Action incorrectly identifies claims 39-59 as pending and rejected. See Office Action at page 2. Only claims 39-58 are currently pending in the present application.

second metallic radiopaque layer and the stent pattern including a plurality of cylindrical elements and interconnecting elements." Applicant respectfully disagrees with the Examiner's interpretation of the references and the rejection of the claims for at least the following reasons.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. M.P.E.P. § 2143.01. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Additionally, a prior art reference must be considered in its entirety. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

A. Richter and Armini Do Not Teach or Suggest a Cladding Layer

Richter and Armini do not teach or suggest all of the elements recited in the instant claim 39 and in claims dependent therefrom. In particular, none of the references teach or suggest the laminate stent comprising a substrate tube having the first and second cladding layers presently claimed.

As one skilled in the art would appreciate, the term "cladding" is a term of art that refers to the bonding together of metals of dissimilar properties under pressure. Cladding is typically achieved by extruding or drawing the cladding metal and the substrate metal through a die.

Furthermore, "a cladding layer formed from a metallic material and bonded to the exterior surface. . ." is typically formed by a drawing process. The specification supports this position, as it describes a process of making a substrate tube for the laminate stent that involves "a deep drawing, cold drawing, or co-drawing on a mandrel." See Specification, pages 4-6 and 10-12.

The differences between the claim laminate stent comprising a substrate tube with cladding layers and the prior art is evidenced by the processes described in the prior art. For example, Richter teaches that a layer of plastically deformable metal is coated on the stent substrate by methods such as "dipping, spraying, vapor deposition, chemical or electrochemical plating, sputtering and the like," preferably by electroplating. See Richter, col. 3, line 60 to col. 4, line 3.

In addition, Armini teaches coating a radiopaque material on a wire substrate, and optionally coating an adhesive layer between the radiopaque material and the substrate material. Armini, col. 4, lines 3-15. The adhesive layer bonds well with both the radiopaque materials, such as gold, as well as the structural materials of a stent, such as stainless steel or nitinol. *Id.* col. 4, lines 5-15. The methods of coating the radiopaque material or the adhesive layer include electroplating, or preferably magentron sputtering. *Id.* col. 5, lines 44-55.

As one skilled in the art would appreciate, neither electroplating nor sputtering is remotely similar to the drawing processes described in the present specification. Significantly, neither of these processes, nor the other coating processes taught in Richter, form cladding layers as claimed. Therefore, one skilled in the art would not

have been motivated to apply the claimed metallic cladding layers by reading Richter and Armini alone or in combination. Furthermore, there would have been no expectation of success in producing the claimed stent since the references relied on never teach cladding layers, and certainly do not disclose methods of making such cladding layers. It is well-known that the prior art can only be modified or combined to reject claims as *prima facie* obvious if there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

These fundamental deficiencies are not cured by the Examiner conclusory assertions that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one material for the an (sic) other within the same art and it would perform equally well in the stent of Richter et al. in view of Armini." Office Action at 3. This position is especially true considering the Examiner admits that neither reference discloses the claimed materials. In other words, the Examiner broad assertions of using the claimed materials as a cladding despite the references collective silence on both the materials and the use of a cladding (as well as the method to make a cladding) do not support his underlying position of obviousness.

Indeed, the Federal Circuit has affirmed its position against such rejections in requiring that evidence of such a suggestion, teaching, or motivation be "clear and particular." *In re Dembiczak*, 175 F.3d 994, 999, 30 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). According to the Federal Circuit in Dembiczak, "[b]road conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Id.* Further, combining prior art references "without evidence of such a suggestion,

teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability - the essence of hindsight." *Id.*

For these reasons alone, the rejection over the combination of Richter and Armini is improper and should be withdrawn.

B. Richter and Armini Do Not Teach or Suggest a Substrate Tube

In addition to the foregoing, the claimed laminate stent is distinct from the prior art in that it comprises a substrate tube that is neither taught nor suggested in the prior art. For example, Armini teaches a stent made of coated wires, not a substrate tube. See Armini, Fig. 1, Fig. 1A, and Fig. 2. Unlike the coated wires described in Armini, the substrate tube of the claimed invention has an inner surface, which may not have a cladding layer, and an outer surface, which has one or more cladding layers. See Specification, page 4, lines 14-20.

Richter is equally as deficient in that it describes a stent body (110) of wires or struts coated with a radiopaque material. See Richter, Fig. 1A and Fig. 1B. Although Richter discloses an embodiment of a stent body covered by tubes (202) or rings (302), the tubes are made of polyurethane, which hold down the stent body at a reduced diameter. *Id.* col. 4, lines 36-53. Furthermore, as previously mentioned, the coating processes described in Richter, e.g. dipping, spraying, vapor deposition, chemical or electrochemical plating, sputtering and the like, at best, forms a coating, not a cladding layer.

While a *prima facie* case of obviousness may arise among materials having close structural similarity, for the reasons described, the stents taught in the cited prior art are not structurally similar to the claimed laminate stents in that they do not contain substrate tube having a first and second cladding layer thereon, as claimed. Thus, these references do not support a *prima facie* case of obviousness. See, *In re Payne*, 606 F.2d 303, 313, 203 U.S.P.Q. 245, 254 (CCPA 1979)(stating "[a]n obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound in the expectation that compounds similar in structure will have similar properties.").

As described in *Payne*, the premise for the presumption of *prima facie* obviousness hinges on the expectation of obtaining similar properties for structurally similar compounds. *Id.* The facts in this case do not support this premise because, not only does the claimed laminate stent comprise materials not taught in the prior art, but it contains such materials in a form not taught or suggested in the prior art. Namely, Richter and Armini individually or in combination do not teach or suggest a substrate tube with a first cladding layer and a second radiopaque cladding layer as recited in claim 39.

For these additional reasons, the Examiner has not established a *prima facie* case of obviousness. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections.

III. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims 39-58.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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